K062302

1. SUBMITTER/510(K) HOLDER

OCT - 6 2006

Millicore AB
Bredgränd 4
111 30 Stockholm
Sweden

Contact Person: Mr. Ola Cornelius
Telephone: +46 (0)70-687 6140

Date Prepared: August 2, 2006

2. DEVICE NAME

Proprietary Name:	DigiVent™ Chest Drainage System
Common/Usual Name:	Chest drainage system
Classification Name:	Bottle, Collection, Vacuum

3. PREDICATE DEVICES

- Express™ Chest Drainage System, Atrium Medical Corp., K984496
- Pleur-evac®, SAHARA, Deknatel DSP Worldwide Inc. (K962856)

4. DEVICE DESCRIPTION

The DigiVent™ Chest Drainage System consists primarily of a collection chamber and a Controller Unit. Pressure regulator, drainage tubing (with kink prevention), positive- and negative pressure relief valves, and hangers complete the system. Thoracic catheters (chest tubes) are not included.

5. INTENDED USE / INDICATION FOR USE

The DigiVent™ Chest Drainage System is indicated to evacuate air and/or fluid from the chest cavity or mediastinum, to help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum, to help re-establish and maintain normal intrathoracic pressure gradients, and to facilitate complete lung re-expansion and restore normal breathing dynamics.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The DigiVent™ Chest Drainage System is substantially equivalent to cited predicate devices based on intended use and operational characteristics. Design verification and validation testing provided in this premarket notification for the DigiVent™ Chest Drainage System demonstrates that it meets its specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Millicore AB
C/O Ms. Rosina Robinson
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K062302
Trade/Device Name: Millicore AB DigiVent™ Chest Drainage System
Regulation Number: 21 CFR 880.6740
Regulation Name: Vacuum-Powered Body Fluid Suction Apparatus
Regulatory Class: II
Product Code: KDQ
Dated: August 2, 2006
Received: August 8, 2006

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: **Millicore AB DigiVent™ Chest Drainage System**

Indications for Use:

The DigiVent™ Chest Drainage System is indicated to evacuate air and/or fluid from the chest cavity or mediastinum, to help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum, to help re-establish and maintain normal intrathoracic pressure gradients, and to facilitate complete lung re-expansion and restore normal breathing dynamics.

Prescription Use ____X____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anthony D. Watson
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K062302